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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,054	03/27/00	ROSEN	N 19962YP

EXAMINER	
GOLDBERG, I	
ART UNIT	**PAPER NUMBER**
1614	10

HM12/1010

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DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/445,054	ROSEN ET AL.	
	Examiner	Art Unit	
	Jerome D Goldberg	1614	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *12-25 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,26-29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 12-25 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicants elected the invention for treating cancer with the enhanced (synergistic) combination of 1-(3-chlorophenyl)-4-[1-(4-cyanobenzyl)-5-imidazolymethyl]-2-piperazinone and paclitaxel for examination on the merits. Applicants' remarks are noted but the other synergistic combinations will support separate patents.

Claims 1-11, 26-29, 31 and 32 are being examined as they read on the elected combination (above).

Claims 1-11, 26-29, 31 and 32 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific therapeutic effect or cancers disclosed, does not reasonably provide enablement for the terms "therapeutic effect" in claims 1-3, 26, 27, 31 and 32 and "cancer" or "cancerous tumors" in claims 4-11, 28 and 29 lack clear examplary support in the specification as filed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The cancer therapy art remains highly unpredictable and no examples exist for efficacy of combination against cancers generally. Therefore, based on the unpredictable nature of the invention and state of the prior art, lack of guidance and working examples, and extreme breadth of the claims, one skilled in this art could not use the entire scope of the claimed invention without

undue experimentation. Changing the above terms to "cancer sensitive to the combination" would overcome this rejection.

Claims 1-7, 10, 11, 26-29, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific antineoplastic agent disclosed , does not reasonably provide enablement for the terms "an antineoplastic agent", "a microtubule-stabilizing agent . . . hematopoietic growth factor "and anthracycline family of drugs . . . podophyllotoxins". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The terms "an antineoplastic agent" in claims 1-5, 10, 11, 26-29, 31 and 32; "a microtubule-stabilizing agent . . . hematopoietic growth factor" in claim 6 and "anthracycline family of drugs . . . podophyllatoxine" in claim 7 lacks clear examplary support in the specification as filed. Changing the term to the elected "paclitaxel" would overcome this rejection.

Claims 1-9, 26-29, 31 and 32 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific prenyl-protein transferase inhibitor disclosed, does not reasonably provide enablement for the term "prenyl-protein transferase inhibitor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "prenyl-protein transferase inhibitor" in claims 1-9, 26-29, 3 and 32 lacks clear examplary support in the specification as filed. Changing the term to the elected compound would overcome this rejection.

Claims 26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26, 28 and 29 are improperly drawn to the same composition. Correction is required. Claims 31 and 32 are improperly drawn to the same methods for forming a composition. Correction is required. Claim 31 and 32 are improperly drawn to the obvious method of preparing a composition by merely mixing the ingredients together. Correction is required.

Claims 26, 28, 29, 30 and 31 fail to recite the amounts of the active agents being employed. Without amounts, the amount of one could be so small as to be meaningless.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 26-29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Anthony et al patent of record taken with the Slichenmyer et al reference.

The Anthony et al. patent teaches applicants' 1-(3-chlorophenyl)-4-[1-(4-cyano benzyl)-5-imidazolylmethyl]-2-piperazinone (col. 19, lines 48-49) for treating cancer (col. 54, lines 50-52) in "human subject" (col. 54, line 61) at 0.1 to 60 mg/kg per day (col. 55, lines 1-4). The Slichenmyer et al reference teaches taxol (paclitaxel) for treating cancers in clinical trials.

The above reference and patent fail to teach specific examples of the old anti-cancer agents together. However, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-cancer agents together, where the results obtained thereby are no more than the additive effects of the ingredients. See In re Sussman 1943 C.D. 518. Claims directed to a showing of greater than the additive effect would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J.D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Tuesday-Thursday from 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 to 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg:mv

October 5, 2001

JEROME D. GOLDBERG
PRIMARY EXAMINER